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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,649	04/08/2004	Aiping H. Young	0018.0024.cip	8794

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EXAMINER	
KOSSON, ROSANNE	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,649	YOUNG, AIPING H.	
	Examiner	Art Unit	
	Rosanne Kosson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-7 and 13-33* is/are pending in the application.

4a) Of the above claim(s) *2-7,13-16,29,30 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-28 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III, claims 17-28 and 31-33, and the species of chemotherapeutic drug (claims 19 and 20) and taxotere (claim 22) in the reply filed on November 4, 2005 is acknowledged. Claims 2-7, 13-16, 29 and 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claim 32 is also withdrawn from prosecution as it recites a non-elected species, taxol.

Claims 18 and 28 have been amended, and no claims have been added or canceled. Accordingly, claims 17-28, 31 and 33 are examined on the merits herewith.

Applicant has traversed the restriction requirement, asserting that it is not a serious burden to search and examine all the pending claims and all the recited species. Applicant also notes that Groups I and III may be classified in the same subclass. In reply, examining all of Applicant's claims and species most certainly does impose a serious burden of search and examination. The searches for the different groups are not coextensive, as the claims in each group recite different claim limitations. The claims in each group have very different considerations with respect to the prior art, as one invention may be anticipated or obvious, while another invention is not. For example, a reference may disclose a composition without disclosing the method by which it is made or for which no data are presented showing that the composition has

therapeutic properties or has successfully treated diseased subjects. Also, the claims in each group have very different considerations under 35 USC §112, as one invention may be enabled or adequately described or claimed in definite terms, while a different invention is not. Regarding classes and subclasses, these are not particularly significant in biotech inventions, as there are not enough subclasses to separate properly the different types of inventions that the Office routinely encounters, for example, a method of manufacturing a drug and a method of treating human or mammalian subjects with that drug. Thus, one subclass may be assigned to groups of claims that constitute very different and patentably distinct inventions. Further, all the claims in an elected invention must be searched and examined. Examiner cannot choose to examine only all of Applicant's generic claims. Searching and examining all of Applicant's recited species is most definitely an undue burden compared to searching and examining the elected species. Therefore, the restriction requirement is deemed proper and is made final.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-21, 23-28 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Rang et al. (WO 96/28175). Rang et al. disclose a method for treating

breast cancer, comprising administering Virulizin® (the commercial name for the low molecular weight bile extract recited in claim 17 and 18) or a composition comprising Virulizin® and a chemotherapeutic agent to subjects with breast tumors (see p. 13, lines 1-17; p. 26, lines 23-30; and p. 28, lines 18-27). If a composition comprising Virulizin® and a chemotherapeutic agent is administered, the two agents must be administered either separately or simultaneously. The Virulizin®-containing compositions of Rang et al. may be formulated as pharmaceutical agents (i.e., pills, tablets, creams, etc.) and administered intramuscularly, intravenously, orally, topically, or by other routes (see p. 27, lines16-37). Virulizin® has the properties that it stimulates monocytes and macrophages and renders them cytotoxic for cancer cells (see p. 13, lines 18-30), it promotes the release of TNF from peripheral blood mononuclear cells (see p. 13, lines 31-37), and the stimulation of monocytes and macrophages is not inhibited by prostaglandins (see p. 78, lines 16-19). Therefore, a holding of anticipation is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17-28, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rang et al. (WO 96/28175) in view of Barlozzari et al. (US 6,103,698)

and DeVita et al. (Cancer: Principles & Practice of Oncology 6th Ed., DeVita, Jr. et al., eds., Lippincott, Williams & Wilkins, Philadelphia, 2001, pp. 292-294). The teachings of Rang et al. are discussed above. Rang et al. do not disclose specifically which additional chemotherapeutic agent is used to treat breast cancer or that the additional chemotherapeutic agent is taxotere. Barlozzari et al. disclose that taxotere may be combined with another chemotherapeutic agent (a Dolastatin-15 derivative) for the treatment of breast cancer or prostate cancer (see col. 3, lines 41-57; col. 4, lines 11-16; and col. 13, lines 23-33). The two drugs may be administered simultaneously or separately (see col. 13, lines 34-49). It would have been obvious to one of ordinary skill in the art at the time that the invention was made to modify the method of Rang et al. to administer a composition comprising Virulizin® and taxotere to treat breast cancer in a mammal, because Rang et al. disclose that Virulizin® and another chemotherapeutic agent may be administered to treat breast cancer. Barlozzari et al. disclose that taxotere and another chemotherapeutic agent may be administered to treat breast cancer. It would have been obvious to one of ordinary skill in the art that both Virulizin® and taxotere are chemotherapeutic drugs for breast cancer that are suitable for administration in combination with another drug, and that, therefore, they would have been administered in combination because treating mammary tumors with this combination would have been more effective than treating mammary tumors with either drug alone. Additionally, DeVita et al. disclose that combination chemotherapy is better than using single drugs alone, because one can achieve maximal cell killing within the range of toxicity tolerated by the host for each drug. Also, it provides a broader range of

interaction between drugs and tumor cells with different genetic abnormalities in a heterogeneous tumor population, and the development of drug resistance is prevented or slowed (see p. 292, 2[d] and 3[d] full paragraphs). In view of the foregoing, a holding of obviousness is required.

Obviousness-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-22, 24, 25 and 31-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-29 of copending Application No. 11/247,026, which has the same inventive entity. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 20-26 and 29 in the copending application are directed to a method of treating any cancer by administering Virulizin® and a chemotherapeutic agent. Claim 27 of the copending application recites that the cancer may be breast or prostate cancer. The process claimed in the instant application differs only in that the

claims do not recite that there is synergy between the two drugs or that the therapeutic index from the treatment is better than the therapeutic index from administering either drug alone. But, it would have been obvious to one of ordinary skill in the art of chemotherapy at the time that the invention was made that if two drugs were administered to a subject to treat a carcinoma, one would have reasonably expected the effect to be better than that obtained by using either drug alone. Also, a method of treating any type of cancer includes methods of treating breast or prostate cancer, particularly as breast and prostate cancer are among the most common types of cancer in adult humans. Thus, the cancer treatment method in the copending application is an obvious variation of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner, Art Unit 1653

rk/2005-11-16

ROBERT A. WAX
PRIMARY EXAMINER